

REMARKS

Claims 1-21 are currently pending in the above captioned application. Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

***Claims Rejections – 35 USC § 103***

*Claims 1-6, 8-9, 11-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Matkovich (5,868,433) in view of Folden (5,221,267).* Applicant respectfully disagrees for reasons set forth below.

The Office Action failed to establish *prima facie* obviousness, because it would not have been obvious for one skilled in the art to combine the Matkovich reference with the Folden reference as suggested by the Examiner. At least one requirement for *prima facie* obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. (MPEP §2142). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. (*Id.*) When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. (*Id.*, citing *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986)).

Matkovich is directed to a connector assembly including mating connectors or fittings that can be coupled together to connect different fluid conduit sections to define a fluid flow path. (Matkovich, col. 4, ll. 57-65). In particular, Matkovich describes that the connector assembly isolates the fluid flow path from the ambient environment, preferably providing a sterile fluid flow path. (*Id.*). In order to achieve this objective, Matkovich describes a special seal or membrane assembly provided to isolate a portion of the fluid flow path prior to mating of the connector. (Col. 5, l. 65 through col. 6, l. 11, see also membrane assemblies 170, 270 of FIG. 1). Thus, each membrane assembly 170, 270 provides a barrier between a respective portion of the fluid flow path and the ambient environment, serving to maintain sterility. These

membrane assemblies are pierced during mating of the connectors to allow fluid communication therebetween. (Col. 13, ll. 36-39, FIG. 7). Matkovich describes that the connectors are preferably positively interlocked when mated to ensure positive contact between containment surfaces. (Col. 8, ll. 40-42, col. 11, ll. 21-27). More particularly, Matkovich describes that an axial restraint resists retraction of a stem, thereby “preventing altogether the retraction of the stem.” (Col. 13, ll. 47-50). Such interlocking of the mated connectors prevents exposure of the fluid channel to the ambient environment after the membranes are pierced.

Folden is directed to a breakable tubing coupling that includes a hollow cylindrical element having a friable section at a position allowing breakable separation by manual bending of the coupling. (Folden, col. 4, ll. 30-32). Thus, after use the coupling is easily broken by bending without the need for scissors or knife. (Col. 4, ll. 35-42). The breakable section is beneficial to allow separation of a fluid delivery system from a patient’s catheter as may be necessary after certain procedures, such as dialysis.

It would not have been obvious, as suggested on page 3 of the Office Action, to add the weakened section of Folden to the modified device of Matkovich in order to allow for a quick disconnect of the connection. The cited references must suggest the desirability of the claimed invention. (MPEP §2143.01(I)). As recited in Applicant’s claims, an irreversible connection for transferring fluid in which “at least one of the connection elements comprises means capable of making it breakable.” Matkovich does not disclose, teach, or suggest any sort of disconnect of the connection, once made. In fact, Matkovich describes that it is preferable to prevent such disconnection -- preventing altogether retraction of the stem. To otherwise break the connection of Matkovich would expose the fluid path to the ambient environment. Matkovich provides special feature to prevent such exposure before and after interconnection. Thus, it would not have been obvious to modify the connectors of Matkovich to include the breakable section of Folden.

Even if the references could be combined as suggested in the Office Action, the possibility of such a combination is not sufficient to render the combination obvious. The mere

fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (MPEP §2143.01(III), citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)). There is no suggestion in the cited references as to the desirability of such a combination.

Moreover, it would not have been obvious to combine the references as suggested in the Office Action, because modification of the connectors of Matkovich to include a breakable section of Folden would jeopardize the intended purpose of the connectors. “If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (MPEP §2143.01(V)). Matkovich describes numerous features to prevent exposure of fluid conduits to the ambient environment. These features include the special membranes and interlocking features. The Office Action suggests that such a modification “would have been obvious to allow for a quick disconnect.” Whereas Folden is directed to applications in which a breakable connection is desirable to allow for a quick disconnect, Matkovich does not suggest any such desirability of disconnecting mated connectors. To the contrary, Matkovich provides features as preferable for preventing any such disconnect. To modify either of the connectors of Matkovich to include a breakable section could lead to an unintentional breakage thereby exposing the fluid conduit to the ambient environment, rendering the connectors of Matkovich unsatisfactory for their intended purpose.

Applicant requests that the rejection with respect to claims 1-6, 8-9, 11-16 and 18-21 be withdrawn, because the Office Action has not established *prima facie* obviousness as it would not have been obvious to one skilled in the art to combine the references as suggested in the Office Action.

*Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matkovich in view of Folden (5,221,267).*

The combination of Matkovich and Folden is improper as argued above. Accordingly, rejection of claims 7 and 10 in view of this same combination is also improper. Applicant requests that the rejection with respect to claims 7 and 10 be withdrawn for the same reasons.

*Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matkovich in view of Folden in further view of Huet (6,595,981).*

Claim 17 depends indirectly from claim 1, thereby including all of the limitations of claim 1. As argued above, the combination of Matkovich and Folden is improper. The addition of Huet with either of the references considered alone fails establish *prima facie* obviousness, because either combination (i.e., Matkovich and Huet or Folden and Huet) fails to disclose, teach, or suggest all of the limitations recited in Applicant's claim. Accordingly, rejection of claim 17 in view of this same combination in further view of Huet is also improper. Applicant requests that the rejection with respect to claim 17 also be withdrawn.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under

Atty. Dkt. No. 079777-0564 (EGS-005/US)

37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account  
No. 19-0741.

Respectfully submitted,

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